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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/731,830 | 12/08/2000 | Junji Hamuro | 200488US0CONT | 6052 |
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| 22850 | 7590 | 04/06/2004 |
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,830

Applicant(s)

HAMURO ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-53, 55, 59, 63, 72, 73, 75-77 and 79 is/are rejected.
- 7) ☒ Claim(s) 54, 56-58, 60-62, 64-71, 74 and 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/334,647; 09/181,881.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/9/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 48-79 are pending.

Applicants' amendment filed on December 23, 2003 is acknowledged. Applicants' response has been fully considered. Claims 30-47 have been cancelled, and new claims 48-79 have been added. Therefore, claims 48-79 are examined.

Foreign Priority

2. A certified English translation of the foreign application (Japan 312727, filed 10/29/97, submitted in application 09/181,881) is acknowledged, and the priority date (October 29, 1997) is perfected.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 30-47, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed December 23, 2003.
4. The previous rejection of claims 30-47, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment to the claim in the amendment filed December 23, 2003.

Claim Rejections - 35 USC § 102&103

5. The previous rejection of claims 30 and 31 under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Peterson *et al.* (Proc. Natl.

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Acad. Sci. USA 95, 3071-3076 (1998)) is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 8 in the amendment filed December 23, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 48-53, 55, 59, 63, 72, 73, 75-77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson *et al.* (WO 91/18594).

Andersson *et al.* teach using cystine compounds such as N,N'-diacetylcystine dimethyl ester (diMeNAC), N,N'-diacetylcystine diethyl ester (diEtNAC), and N,N'-diisovalerylcystine dimethyl ester (diMeVAL; page 3, line 31-page 4, line 33; claims 72, 73, 75-77 and 79) in an effective amount to treat diseases where a defect in the immune system such as chronic bronchitis and other inflammatory diseases of airway, certain autoimmune diseases such as rheumatoid arthritis (claims 55, 59 and 63) and various malignant diseases by administering to a host in need of such treatment (page 6; claim 24 of the WO document; claims 48-53). Since the reference teaches using the same amount of cystine compound (0.5-500 mg/day; page 9, line 1) as the instant application (1-5000 mg/day; page 19, lines 10-11 of the specification) to administer to a subject, it would be expected to reduce the content of reductive glutathione in macrophage in the subject, to increase the capability of the macrophage to produce IL-6, and to decrease the capability of the macrophage to produce IL-12 and NO for the method of inducing a Th2 response in a subject; or to reduce the content of reductive glutathione in macrophage in the

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subject for the method of suppressing cellular immune responses in a subject, thus the teachings of the reference anticipate the claimed invention.

7. Claims 54, 56-58, 60-62, 64-71, 74 and 78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Claims 48-53, 55, 59, 63, 72, 73, 75-77 and 79 are rejected, and claims 54, 56-58, 60-62, 64-71, 74 and 78 are objected to.

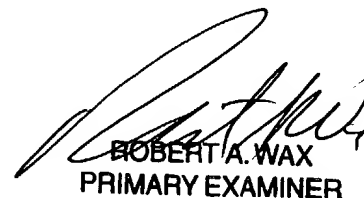
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 25, 2004


ROBERT A. WAX
PRIMARY EXAMINER